"Pathways to Global Unity"

SATURDAY, JUNE 9, 2018

7:30 am – 8:45 am	**Continental Breakfast** | **Location:** Emerald Ballroom Promenade
8:00 am – 12:00 pm	**Environmental Sampling as a Tool for Solving Outbreaks at the Retail Food Level | Location:** Emerald III Ballroom Environmental samples can often link an illness to establishment for a period of time after food is no longer available. Learn more about how to conduct environmental sampling in retail food (restaurants, grocery, etc.) for outbreak investigations including practical exercises. *Steven Mandernach, Bureau Chief for Food and Consumer Safety, Iowa Department of Inspections & Appeals* *Vincent Radke, Sanitarian, Centers for Disease Control and Prevention* *Douglas Irving, EHS-Net Food Coordinator, Tennessee Department of Health* *Danny Ripley, Environmental Health Specialist, Metro Nashville Public Health Department* *David Nicholas, MPH, Chief Epidemiologist, New York State Department of Health* *Yvonne Salfinger, Project Manager, Laboratory Accreditation, Association of Food and Drug Officials* **Sample materials donated by:** Puritan Quality since 1919 · world bioproducts · HALYARD
9:00 am – 12:00 pm	**Getting a Seat at the Table - The Effective Regulator: A Workshop on Improving Your Communication Skills | Location:** Emerald I Ballroom Join Nancy Singer, JD, LLM, RAC and Daniela Drago, PhD, RAC assistant professors at George Washington School of Medicine and Health Sciences, prominent retired AFDO alumni, and current members in an interactive session where you will discover key communication skills that will improve your performance in the workplace. Topics to be covered include: the essentials skills required by regulators; how to project an image of authority and competence; ways to handle difficult situations gracefully; and email techniques to motivate people to take action. *Daniela Drago, PhD, RAC, Assistant Professor, George Washington School of Medicine and Health Sciences*
8:00 am – 12:00 pm	**HACCP System Implementation, A Guide for Inspectors | Location:** Emerald II Ballroom Once a HACCP plan has been approved, what must a restaurant/retailer engaging in a specialized processing method do to implement the plan successfully? In this workshop, we dive into HACCP record keeping requirements and verification activities and discuss how to overcome challenges posed by limited resources, seasonal menus and rotating suppliers. Deliverables from this workshop include strategies for enforcement of HACCP requirement and deeper understanding of HACCP system implementation in the retail/food service environment. *Charlie Kalish, Managing Member, Food Safety Guides* *Michael Kalish, Managing Member, Food Safety Guides*
10:00 am – 10:30 am	**Break / Exhibitor Showcase** | **Location:** Emerald Ballroom Promenade
11:30 am – 1:30 pm	**Lunch On Your Own- Cash-N-Carry Lunches will be Available** | **Location:** G's Restaurant

AFDO Committee Meetings are open to all Conference Attendees

12:30 pm – 2:00 pm	**Food Committee** | **Location:** Lake Champlain Exhibition Hall **Guest Speakers/Presentations:** **Introduction** **Update on Training from FDA** *Patricia Alcock, Director, Division of Human Resource Development, U.S. Food and Drug Administration (via webinar)* **Update of MFRPA Training Activities** *Patrick Kennelly, Program Director, Association of Food and Drug Officials* **The National Food Safety Data Exchange - Drew Polulak and Zhensen Huang** *Andrew Polulak, Business Development Director, Computer Aid, Inc.* *Zhensen Huang, CEO, Precise Software Solutions* **Report out of Committee Activities for the current year and review of deliverables for next year**

Join AFDO on Social Media

Facebook.com/Associationoffoodanddrugofficials

Association of Food and Drug Officials

@afdonews

afdoconnects

#AFDO2018

As of 6/04/18

Ticket required

2:00 pm – 4:00 pm	**Retail Food Committee** | **Location:** Lake Champlain Exhibition Hall **Guest Speakers/Presentations:** **USDA Update** *Carl-Martin Ruiz, Deputy Assistant Administrator, Office of Investigation, Enforcement and Audit (OIEA), Food Safety and Inspection Service, U.S Department of Agriculture* *Elaine Hite, Program Specialist, Food Safety and Inspection Service, U.S Department of Agriculture* **Grinding Recordkeeping Requirement: Policy & Observations from Enforcement** *William K. Shaw, Jr., PhD., Director, Risks, Innovations, and Management, Office of Policy and Program Development, Food Safety and Inspection Service, U.S Department of Agriculture* *Thomas Collaro, Senior Compliance Investigator, Office of Investigation, Enforcement and Audits, Food Safety and Inspection Service, U.S. Department of Agriculture* **CFP Update** *Patrick Guzzle, Food Protection Program Manager, Idaho Department of Health and Welfare* **FDA Food Code Update** *Glenda Lewis, M.S.P.H., Director, Retail Food Protection Staff, CFSAN, U.S. Food and Drug Administration* **An innovative hands-on approach to food safety training** *Robert Mancini, Environmental Health Officer, Health Canada*
4:00 pm – 5:30 pm	**Produce Committee** | **Location:** Diamond Ballroom **Guest Speakers/Presentations:** **Intro of Co-Chairs and Request for Members** **Vermont's Funding Model for Farmers to meet the Requirements of FSMA, specifically the Produce Safety Rule** *Abbey Willard, Agricultural Development Division Director, Vermont Department of Agriculture, Food & Markets* **Development of the Michigan Food Safety Working Group for Group GAP to Regional Food Hubs and Beyond** *Jennifer Silveri, Director of Field Operations, Michigan Food & Farming Systems (MIFFS)* **Q&A for Speakers** **Review of Charges** **Request for Members**
5:30 pm – 6:30 pm	**AFDO Committee Chairs and Co-Chairs Meeting** | **Location:** Emerald I Ballroom

SUNDAY, JUNE 10, 2018	
7:30 am – 9:30 am	**Continental Breakfast** | **Location:** Emerald Ballroom Promenade
AFDO Committee Meetings are open to all Conference Attendees	
8:00 am – 9:00 am	**Endowment Foundation** | **Location**: Diamond I Ballroom
8:00 am – 9:30 am	**Food Protection & Defense Committee** | **Location:** Emerald III Ballroom **Guest Speaker/Presentation:** **Emergency Response Guide Reveal** **Charges Review** **Genomics as a Countermeasure to Food Defense** *Robert Hanner, PhD, Associate Professor, Biodiversity Institute of Ontario, University of Guelph* **FDA IA Rule Update** *Colin Barthel, Office of Food Defense, U.S. Food and Drug Administration*
9:00 am – 10:00 am	**Industry Associate Membership Committee** | **Location:** Diamond I Ballroom
9:00 am – 10:00 am	**Administrative Committee** | **Location:** Kingsland
10:00 am – 11:30 am	**Break / Exhibitor Showcase** | **Location:** Emerald Ballroom Promenade
9:30 am – 11:00 am	**Foodborne Outbreak & Emergency Response Committee** | **Location:** Emerald III Ballroom **Guest Speaker/Presentation:** **Welcome & Committee Update** *Alida Sorenson, Response and Recall Coordinator, Minnesota Department of Agriculture* *Karen Blickenstaff, Team Lead, CORE, U.S. Food and Drug Administration* **New CORE Director Introduction** *Dr. Stic Harris, CORE Director, U.S. Food and Drug Administration* **CORE Updates** *Karen Blickenstaff, Team Lead, CORE, U.S. Food and Drug Administration* **RRT Updates** *Priscilla Neves, Consumer Safety Officer, U.S. Food and Drug Administration* **Cottage Foods & Norovirus** *Alida Sorenson, Response and Recall Coordinator, Minnesota Department of Agriculture* **FoodSHIELD Update** *Penny Norquist, Program Manager, Food Protection and Defense Institute*

Ticket required

10:30 am – 12:00 pm	**Drugs, Devices & Cosmetics Committee** | **Location:** Lake Champlain Exhibition Hall **Guest Speaker/Presentation:** **Dermal Abyss: Tattoos as medical condition monitors** *Ali K. Yetisen, PhD, Principal Investigator, The University of Birmingham*
10:30 am – 11:30 pm	**Laboratory, Science and Technology Committee Meeting** | **Location:** Emerald I Ballroom **Guest Speaker/Presentation:** **NYSDAM/FDA Mutual Reliance Pilot Update** *Maria Ishida, Director of Division, Food Laboratory, New York Department of Agriculture and Markets* *Ron Pace, District Director, U.S. Food and Drug Administration*
11:00 am – 12:00 pm	**Professional Development Committee** | **Location:** Diamond I Ballroom
11:30 pm – 12:30 pm	**Seafood Committee** | **Location:** Emerald I Ballroom **Guest Speaker/Presentation:** **Welcome and Updates** *Rita Johnson, Biological Scientist IV, Division of Food Safety, Florida Department of Agriculture and Consumer Services* *Courtney Mickiewicz, Regional Manager, Food Safety & Security Program, Virginia Department of Agriculture and Consumer Services* **Control of Pathogens in Ready-to-Eat Seafood Products: Introduction to Industry Manual** *Lisa Weddig, Vice President, Regulatory and Technical Affairs, National Fisheries Institute* **Updates from U.S. Food and Drug Administration** *Steven Bloodgood, Chief, Seafood Processing & Technology Policy Branch, Division of Seafood Safety, CFSAN, U.S. Food and Drug Administration* **Questions/Discussion**
11:30 am – 1:30 pm	**Lunch On Your Own - Cash-N-Carry Lunches will be Available** | **Location:** G's Restaurant
12:30 pm – 1:30 pm	**Cannabis Committee | Location:** Emerald I Ballroom **Guest Speaker/Presentation:** **Overview of U.S. Cannabis status will include Canada.** **Discussion on Cannabis issues/concerns related to inclusion in traditional food and dietary supplement products** **Discussion of outlining "Best Practices for Edible Product Production" or something similar to AFDO's Cottage Food Model** **Recruitment of Committee members** **Promotion of the Cannabis sessions during the conference**
12:30 pm – 1:30 pm	**Laws & Regulations Committee** | **Location:** Amphitheatre **Guest Speaker/Presentation:** **Regulating Alcoholic Beverages in Minnesota** *Katherine Simon, Assistant Division Director, Food & Feed Safety Division, Minnesota Department of Agriculture*
12:30 pm – 3:30 pm	**Body Art Committee** | **Location:** Lake Champlain Exhibition Hall **Guest Speaker/Presentation:** **Update on Body Art Committee Activities** *Ken Coleman Stevenson II, VP Regulatory Affairs, Ceutical Laboratories, Inc* **Inspection Basics for Body Art Establishments** *Sarah Robbin, AFDO Body Art Committee Chair,* *Laurel Arrigona, Regulatory Affairs, Ceutical Labs Inc* *Steve Joyner, Legislation and Regulatory Affairs, Association of Professional Piercers* *Matt Bavougian, Legislation and Regulatory Affairs Committee Member, Association of Professional Piercers*
1:30 pm – 3:30 pm	**International & Government Relations Committee** | **Location:** Amphitheatre **Moderators:** *Ken Moore, Special Advisor, Health Product Compliance Directorate, Health Canada* *LaTonya Mitchell, District Director, U.S. Food and Drug Administration* **Guest Speaker/Presentation:** **An Overview of International Recognition Systems** *Mark Abdoo, Acting Deputy Commissioner for Global Regulatory Operations and Policy, U.S. Food and Drug Administration* **System's Recognition Implementation Panel** **Office of Regulatory Affairs (ORA) perspective** - *Bruce Ross, Supervisor, International and Federal Engagement Office of Partnerships, ORA, U.S. Food and Drug Administration* **Canadian Food Inspection Agency (CFIA) perspective** - *Nicole Bouchard-Steeves, Executive Director, Operations Modernization Project Office, Canadian Food Inspection Agency* **Audit Program** - *Ellen Buchanan, Audit Director, Office of Human and Animal Food Operations, ORA, U.S. Food and Drug Administration* **Mutual Recognition for Pharmaceuticals** **Health Canada Perspective** - *Kimby Barton, Director, Health Product Inspection and Licensing, Health Canada*

Ticket required

1:30 pm – 3:30 pm	**Partners with a Common Purpose** | **Location:** Diamond Ballroom The concept of "Partners with a Common Purpose" recognizes that establishing equal partnerships and collaborating at meetings and forums will generate greater input for continuously improving food safety and public health. One of AFDO's primary roles in this initiative is to ensure there is broad agreement on the common purpose and that all stakeholders are engaged. During this session, industry food safety professionals and regulatory officials will engage with each other in a facilitated "safe-harbor" environment as they examine their ability to impact food safety control through self-examination, discussions and forums. Discussions might include, but are not limited to the elements of successful programs, barriers in implementing intervention strategies, lessons learned, sharing of best practices, and future challenges and opportunities. *Joe Corby, Executive Director, Association of Food and Drug Officials* *Mark Miklos, Program Director, Member Engagement, National Restaurant Association* *Courtney Mickiewicz, Regional Manager, Virginia Department of Agriculture and Consumer Services* *Jessica Badour, Recall Outreach Specialist, Food Safety Division, Georgia Department of Agriculture* *Dionne Crawford, Food Safety Manager, US Supply Chain Management, McDonald's USA, LLC*
2:00 pm – 3:00 pm	**Alumni/ Professional Development Committee** | **Location:** Willsboro
3:00 pm – 4:00 pm	**Break / Exhibitor Showcase** | **Location:** Emerald Ballroom Promenade
3:30 pm – 4:20 pm	**First Time Attendee Welcome Reception** | **Location:** Emerald I & II Ballroom AFDO considers first time attendees to be VIPs at the Annual AFDO Conference. If this is your first AFDO meeting, the AFDO alumni and fellows invite you to attend the First Time Attendee Welcome Reception that is being held in your honor. During the session, you will have the opportunity to meet AFDO alumni and other first time attendees; enjoy refreshments; learn about AFDO and its affiliate organizations; and find out about the exciting events that will take place during the 2018 conference.
4:30 pm – 6:00 pm	**Opening Session** | **Location:** Emerald III Ballroom *Pamela Miles, AFDO President and Program Supervisor, Virginia Department of Agriculture and Consumer Services* **Invocation** *Rev. Ken White, Pastor, College Street Congregational Church* **Welcome from Burlington** *Terence Macaig, Vermont State Representative, Chittenden-2.* **Welcome from NEFDOA** *Elisabeth Wirsing, MPH, Food and Lodging Program Chief, Vermont Department of Health* **Endowment Foundation Address** *John Young, Chair, AFDO Endowment Foundation, and Partner, Young & Associates* **President's Address** *Pamela Miles, AFDO President and Program Supervisor, Virginia Department of Agriculture and Consumer Services* **Glenn W. Kilpatrick Memorial Address** *Sandra Eskin, Director, Food Safety, The Pew Charitable Trusts*
6:00 pm – 7:30 pm	**Welcome Reception | Location:** Lake Champlain Exhibition Hall Sponsored by the AFDO Associate Members and the North East Food and Drug Officials Association (NEFDOA) Thank you to all our contributing Industry Sponsors. ***All are welcome to attend!***
8:00 pm – 10:00 pm	**AFDO Trivia & Karaoke | Location:** Diamond Ballroom Join in the fun to learn some new information, potentially win some valuable prizes and, of course, raise money for the Endowment Foundation all while listening to the talents of fellow conference attendees. Sponsored by General Mills

Ticket required

Food Sessions

Monday, June 11, 2018

Morning Joint Session

Moderator: Laurie Farmer, Director Office of State Cooperative Programs, U.S. Food and Drug Administration

7:30 am - 9:00 am — **Continental Breakfast** | **Location:** Emerald Ballroom Promenade

8:00 am - 8:15 am — **Announcements & Awards** | **Location:** Emerald Ballroom
Pamela Miles, AFDO President and Program Supervisor, Virginia Department of Agriculture and Consumer Services

8:15 am – 9:30 am — **U.S. Food and Drug Administration Regulatory Affairs Update** | **Location:** Emerald Ballroom
ORA's senior leaders will provide an update on significant operational changes and how things are working in the new program aligned organizational structure. They will also share information about key programmatic initiatives, as well as participate in a panel discussion with attendees.
Melinda Plaisier, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration
Michael Rogers, MS, Assistant Commissioner for Human and Animal Food Operations, U.S. Food and Drug Administration
Erik Mettler, MPA, MPH, Assistant Commissioner for Partnerships and Policy, U.S. Food and Drug Administration
Alonza Cruse, Director, Office of Pharmaceutical Quality Operations, U.S. Food and Drug Administration
Armando Zamora, Acting Director, Office of Enforcement and Import Operations, U.S. Food and Drug Administration

9:30 am – 10:00 am — **Hurricane Maria and Puerto Rico's Response to Regulated Food and Drug Firms** | **Location:** Emerald Ballroom
Hurricane Maria is regarded as the worst natural disaster on record in Puerto Rico. The tenth-most intense Atlantic hurricane on record and the most intense tropical cyclone worldwide of 2017. This session focuses on the challenges presented in the FDA regulated products arena during this hurricane.
Nicholas Scire, Consumer Safety Officer, U.S. Food and Drug Administration

10:00 am - 10:30 am — **Break / Exhibitor Showcase** | **Location:** Emerald Ballroom Promenade

Moderator: Randy Treadwell, Program Manager, Rapid Response & Emergency Management, Washington State Department of Agriculture

10:30 am - 11:15 am — **FSIS Policy Update** | **Location:** Emerald Ballroom
Roberta Wagner, Assistant Administrator, Office of Policy and Program Development, U.S. Department of Agriculture

11:15 am – 12:00 pm — **Meet Irma and Harvey** | **Location:** Emerald Ballroom
Hurricane Harvey is tied with Hurricane Katrina as the costliest tropical cyclone on record, inflicting at least $125 billion (2017 USD) in damage, primarily from catastrophic rainfall-triggered flooding in the Houston metropolitan area. Hurricane Irma is one of the most powerful Atlantic hurricanes ever recorded in the Caribbean and Florida. This session with focus on best practices learned during the response to Irma & Harvey.
Moderators:
Randy Treadwell, Animal Feed/Rapid Response Program Manager, Washington State Department of Agriculture
Alida Sorenson, Response and Recall Coordinator, Minnesota Department of Agriculture
Panelists:
Summer Williams, Rapid Response Team Coordinator, Florida Department of Agriculture & Consumer Services
Tishara Coleman, Texas Rapid Response Team Project Specialist, Texas Department of State Health Services
Rebecca Dreisch, National Emergency Response Coordinator, ACHAFO, U.S. Food and Drug Administration

12:00 pm – 1:30 pm — **Lunch On Your Own - Cash-N-Carry Lunches will be Available** | **Location:** G's Restaurant

12:00 pm - 1:30 pm — **Burditt Lunch** | **Location:** Lake Champlain Exhibition Hall
Take a fun filled journey into AFDO's past, present and future. Your first stop will be 1915 where you will meet prominent AFDO members and supporters and hear their exact words that were delivered at the 19th Annual Conference held in Berkeley, California. A number of important actions and Resolutions came out of this conference including the association's expression of concern for misleading packaging, continued support for federal state cooperation, and a Resolution recommending states enact food safety requirements for all public eating establishments. Following a short visit to 1917 and 1943, we will salute all former and current Women who served as AFDO Presidents. Finally, we take a journey into the AFDO future to witness some very entertaining and interesting events.

Breakouts (Choose 1)

FOOD BREAKOUT | **Location:** Emerald III Ballroom

Moderator: Steven Mandernach, Bureau Chief for Food and Consumer Safety, Iowa Department of Inspections and Appeals

1:30 pm – 2:30 pm — **Food Safety on the Little Screen**
Examine compliance with recommended food safety practices in television cooking shows and learn first-hand about the safety experiences from the 7th season of Food Networks "The Great Food Truck Race" winners.
Nancy Cohen, Ph.D., RD, FAND, Senior Planning Officer, Professor of Nutrition, University of Massachusetts Amherst
Kim Concra, Nutrition and Food Safety Specialist, Cape Cod Cooperative Extension, University of Massachusetts, Amherst
Charlie Kalish, Managing Member, Food Safety Guides

2:30 pm – 3:15 pm — **What's Ready-to-Eat?**
Flour, frozen vegetables and other products that have not traditionally been consider ready to eat food have recently resulted in massive nationwide recalls. Join this panel to explore the question of "what is ready-to-eat"?
Courtney Bidney, Director, Global Scientific and Regulatory Affairs, General Mills
Donna Garren, PhD., Executive Vice President, Science & Policy, American Frozen Food Institute (AFFI)
Mickey Parish, Ph.D., Senior Science Advisor, CFSAN, U.S. Food and Drug Administration

3:15 pm – 3:45 pm — **Break / Exhibitor Showcase** | **Location:** Emerald Ballroom Promenade

As of 6/04/18

Ticket required

RETAIL BREAKOUT | **Location:** Emerald I & II Ballroom

1:30 pm – 2:45pm | **Investigators' Discoveries: Digging Deeper for Food Safety**

Hands-on, interactive exercise where participants will view photos and use illustrated scenarios to practice the "What, Where, When, Why, Who and How" while initiating a risk-based approach to the inspection and seek root causes. Participants will walk away with a "training tool" to train other staff in the art of risk-based inspections and root case analysis.

Moderator: Barbara Kitay, U.S. Food and Drug Administration

Jennifer Pierquet, Program Planner, Iowa Department of Inspection & Appeals

Mark Speltz, Retail Program Lead/Training Specialist, Iowa Department of Inspection & Appeals

2:45 pm – 3:15 pm | **Break / Exhibitor Showcase** | **Location:** Emerald Ballroom Promenade

BREAKOUTS (CHOOSE 1)

FOOD BREAKOUT | **Location:** Emerald III Ballroom

Moderator: Joseph Corby, Executive Director, Association of Food and Drug Officials

3:45 pm – 4:30 pm | **Listeriosis Prevention: It's a Collaborative Effort**

Advancing food safety and mitigating the risk of Listeria monocytogenes (Lm) in the food and beverage industry is a shared goal of both industry and regulatory agencies. During the panel discussion, the panelists and attendees will discuss the development of practical, science-based regulatory approaches to address Lm in manufacturing and retail environments and in foods. In addition, panelists will highlight what additional research and risk assessments may still be needed to achieve these shared Lm public health goals and help guide industry and regulatory policy development in the US.

Donna Garren, PhD., Executive Vice President, Science & Policy, American Frozen Food Institute (AFFI)

Mickey Parish, Ph.D., Senior Science Advisor, CFSAN, U.S. Food and Drug Administration

4:30 pm – 5:30 pm | **Food Recovery Systems**

In recent years, there have been growing concerns about food waste. To make better use of the food resources available in the community, food recovery systems provide meals for the people in need and minimizes food waste at the same time. A few years ago, the Food and Agriculture Organization (FAO) estimated that each year one third of all food produced for human consumption in the world is lost or wasted, and this represents an enormous missed opportunity to improve global food security. Panelists will discuss their important roles in the food recovery system and how food safety influences these roles.

Mitzi Baum, M.Sc, Managing Director of Food Safety, Feeding America

Christine Beling, Project Engineer, Assistance and Pollution Prevention Unit, U.S. Environmental Protection Agency

Jason Maring, Chief Operations Officer, Vermont Foodbank

RETAIL BREAKOUT | **Location:** Lake Champlain Exhibition Hall

3:15 pm – 5:30 pm | **Retail "Speed Dating" Session**

Join us in celebrating the successful implementation of the Retail Program Standards and you can get tips on how they did it. FDA and CFSAN, along with State and local governments will exhibit projects and tools developed to help implement and conform to the Retail Program Standards. You will have the opportunity to visit numerous tables, each representing a different Retail Standard or different stage of implementation of the Standards. There is something for everyone, from the newly enrolled to those who have made some progress and who are working toward continuous improvement.

Moderators: *Cathy Hosman, Project Officer, Office of Partnerships, U.S. Food and Drug Administration*
Peter Salsbury, Project Manager, CFSAN, Retail Food Partnerships, U.S. Food and Drug Administration

Improve Your Food Protection Program – It's as Easy as P….T….V:

Dawn Beck, Associate Director of Public Health, Olmsted County Public Health Services, Minnesota

Targeting Holding Time and Temperature:

Katie Lott, RS, Program Manager, Food & Community Safety, Tacoma-Pierce Health Department, Washington

A Two Front War on Risk Factors:

Mark Speltz, Chief Inspector, Iowa Department of Inspection & Appeals

"The Wheelhouse" offering a great selection at low-low prices (free) don't reinvent the wheel – we already have the one you need:

Gary Coggins, Environmental Health Manager, New River Health District, Virginia Department of Health

Pete Salsbury, Project Manager, CFSAN, Retail Food Partnerships, U.S. Food and Drug Administration

UFE's (Unattended Food Establishments) Do Exist!:

Adam Inman, Assistant Program Manager, Kansas Department of Agriculture

Recall Audit Check – Just in Time Training Module:

Summer Williams, Emergency Response Coordinator, Division of Food Safety, Florida Department of Agriculture & Consumer Services

Stronger Together…a Regional Approach to a Uniform Food Safety Inspection Program:

Jayne E Smith, RS, Berkshire Public Health Alliance Inspector, Egremont, Massachusetts

Links to Success….Violation Hyperlinks to Eliminate Hazards:

Catherine Feeney, MBA, RD, LDN, Chief, Center for Food Protection, Rhode Island Department of Health, Providence, Rhode Island

6:00 pm – 10:00 pm | **MONDAY NIGHT EVENT: "ENJOY THE JOURNEY"**

Join us for a Sunset Dinner Cruise on Lake Champlain aboard the Spirit of Ethan Allen. A sumptuous buffet dinner, music, and a memorable evening awaits. The dining area is enclosed and fully climate controlled, but there is plenty of room on deck to enjoy the views of the Adirondack's, Green Mountains, Burlington and possibly a sighting of our lake monster "Champ." Be sure to have your camera ready. "It's always a beautiful day on the lake."

Sponsored in part by the National Restaurant Association

Ticket required

TUESDAY, JUNE 12, 2018

MORNING JOINT SESSION

Moderator: Peter Salsbury, Project Manager, U.S. Food and Drug Administration

7:30 am - 9:00 am	**Continental Breakfast** | **Location:** Emerald Ballroom Promenade
8:00 am - 8:15 am	**Announcements & Business Meeting** | **Location:** Emerald Ballroom *Pamela Miles, AFDO President and Program Supervisor, Virginia Department of Agriculture and Consumer Services*
8:15 am – 8:45 am	**Public Health Crisis of Opioid Addiction** Communities all across the country have been facing the challenge of opioid addiction. Learn more about the four-year-old Hub and Spoke system in Vermont that has made a significant positive impact in many important personal and public health and safety indicators, and how this evidence-based work relates to regional and national public health efforts. *Mark Levine, MD, Commissioner, Vermont Department of Health*
8:45 am - 9:15 am	**Children with Intractable Seizures: The History of Cannabidiol and GW Pharmaceuticals** The political environment in the late 1990s with regard to attitudes toward cannabis, in both the U.S. and the U.K., was very different than it is now. A number of factors coalesced to make it possible for GW Pharmaceuticals (now Greenwich Biosciences in the U.S.) to be founded, making it the first company in the world to attempt to develop cannabis-derived prescription medications in accordance with regulatory standards for conventional pharmaceutical products. Since that time, significant research has been conducted, including robust preclinical research on cannabidiol (CBD) demonstrating in multiple animal models that CBD had anti-convulsant properties. This led patients and physicians to request CBD from GW, which resulted in the largest physician-initiated expanded (compassionate) access program in FDA's history and culminated in the first major randomized, placebo-controlled, double-blind clinical trial (RCT) program to have been conducted on CBD. *Alice Mead, Vice President of US Public Policy and Public Affairs for GW Pharma, Greenwich Biosciences*
9:15 am - 10:15 am	**Data Integrity** FDA depends heavily on the integrity of data generated in support of pre-approved applications and to confirm that medical products are manufactured in a manner to ensure their safety and effectiveness. This presentation will discuss the critical element of data integrity, data integrity and 21 CFR Part 11, FDA's increasing interest focusing on data reviews during surveillance inspections and recent FDA findings of data integrity issues. *Mike Chappell, Principal, Regulatory Compliance, Greenleaf Health LLC*
10:15 am – 10:30 am	**Break / Exhibitor Showcase** | **Location:** Emerald Ballroom Promenade

Moderator: Peter Salsbury, Project Manager, U.S. Food and Drug Administration

10:30 am – 11:00 am	**U.S. Food and Drug Administration's Food Program Update** | **Location:** Emerald Ballroom

Building partnerships at home and abroad, Dr. Stephen Ostroff, FDA's Deputy Commissioner for Foods and Veterinary Medicine, talks about how FDA is working with state, tribal and foreign regulatory counterparts to implement the FDA Food Safety Modernization Act. He will provide an update on FSMA implementation and the work the agency is doing to ensure parity in the oversight of domestic and imported foods.

Dr. Stephen Ostroff, Deputy Commissioner for Foods and Veterinary Medicine, Office of Foods and Veterinary Medicine, U.S. Food and Drug Administration

11:00 am – 12:00 pm	**Why??? | Location:** Emerald Ballroom

Understanding why a breakdown in the food system occurred is an emerging trend in foodborne illness and food incident investigations. Learn about multiple projects focused on getting to "WHY" the incident happened.

Erik W. Coleman, MPH, Health Scientist (Informatics), National Center for Environmental Health, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services

Carol Conroy, Associate, Safe Food Project, The Pew Charitable Trusts

Carla Tuite, MS, LCDR, US Public Health Service, Human and Animal Food Policy Branch, Office of Strategic Planning and Operational Policy, ORA, U.S. Food and Drug Administration

12:00 pm – 1:30 pm	**Lunch On Your Own - Cash-N-Carry Lunches will be Available** | **Location:** G's Restaurant

NEHA Continuing Education Units

Available ***on*** Tuesday, June 12, 2018

See Registration Desk for more information

As of 6/04/18

Ticket required

BREAKOUTS (CHOOSE 1)

Food Breakout | **Location:** Emerald III Ballroom

1:30 pm – 2:00 pm | **Moving Towards a Public Health Systems Approach**

FDA's public health mandate, an overview of a public health inspection process. This session will also include an update on new developments on Sanitary Transportation and Intentional Adulteration rules.

Moderator: Peter Salsbury, Project Manager, U.S. Food and Drug Administration

Joann Givens, Director, Office of Human and Animal Food Operations, U.S. Food and Drug Administration

2:00 pm – 3:00 pm | **A Conversation with the Experts on Produce Safety**

This panel incudes experts from FDA, States and the Produce Safety Alliance.

Moderator: Bob Ehart, Senior Policy & Science Advisor, National Association of State Departments of Agriculture (NASDA)

Samir Assar, Ph.D., Director of the Office of Produce Safety, CFSAN, U.S. Food and Drug Administration
Elizabeth Bihn, Ph.D., Director, Produce Safety Alliance, Cornell University
Kristin Esch, Produce Specialist, Michigan Dept. of Agriculture and Rural Development
Joseph Reardon, Assistant Commissioner of Consumer Protection, North Carolina Depart of Agriculture and Consumer Services

Retail Breakout | **Location:** Emerald I & II Ballroom

1:30 pm – 3:00 pm | **The Culture of Change….How to get better at getting better.**

A discussion of how can we frame our food safety conversations to be understood by people of all generations and backgrounds to achieve behavioral change.

Moderator: Dionne Crawford, Food Safety Manager, US Supply Chain Management, McDonald's USA, LLC

Benjamin Chapman, Ph.D., Associate Professor, Food Safety Specialist, Department of Agricultural and Human Sciences, North Carolina State University

3:00 pm – 3:30 pm | **Break / Exhibitor Showcase** | **Location:** Emerald Ballroom Promenade

BREAKOUTS (CHOOSE 1)

Food Breakout | **Location:** Emerald III Ballroom

Moderator: Patrick Kennelly, Program Director, Association of Food and Drug Officials

3:30 pm – 4:15 pm | **FSMA Imports and Systems Recognition**

FDA will provide an overview of the import provisions in the FDA Food Safety Modernization Act. The focus will be on the Foreign Supplier Verification Program, the Voluntary Qualified Importer Program, and the Accredited Third-Party Certification Program, including an overview of the implementation status of these programs.

Sharon Mayl, Senior Advisor for Policy, U.S. Food and Drug Administration

4:15 pm – 5:30 pm | **Preventive Controls: Moving Food Safety into the 21st Century**

This panel includes FDA, State and Industry Representative discussing the implementation and lessons learned.

Matthew Coleman, Environmental Administrator, Florida Department of Agriculture and Consumer Services
Joann Givens, Director, Office of Human and Animal Food Operations, U.S. Food and Drug Administration
Jan Kelly, Manufactured Food Program Manager, Minnesota Department of Agriculture
Kristen Spotz, Senior Manager, Food Safety and QY Manager, Grocery Manufacturers Association

Retail Breakout | **Location:** Emerald I & II Ballroom

3:30 pm – 5:30 pm | **Alexa, Bring Me Dinner**

At home delivery is no longer just pizza and Chinese. Today you can get meal kits, groceries, gourmet dinners, or a Big Mac delivered to your door. Learn more about the food safety concerns in this new age of delivery and how industry has met these challenges.

Moderator: Glenda Lewis, Director, M.S.P.H. Retail Food Protection Staff, CFSAN, U.S. Food and Drug Administration

Dr. John M. Ryan, Ph.D. PCQI, Ryan Systems, Inc
Christina Bongo-Box, Little Caesars Enterprises, Inc, Co-Chair of the Conference for Food Protection Mail Order Food Safety Committee
Valerie Madamba, Food Regulatory Counsel, Blue Apron, LLC
Cory Hedman, VP, Food Safety & Quality Assurance, Meijer, Inc.

5:30 pm – 6:30 pm | **NEFDOA Board Meeting | Location:** Kingsland

6:30 pm – 7:30 pm | **President's Reception | Location:** G's Restaurant

7:30 pm – 9:30 pm | **Wiley Award Banquet | Location:** Lake Champlain Exhibition Hall

Check out *the* Presentations

Presentations will be posted on the conference website following the conference

As of 6/04/18

Ticket required

WEDNESDAY, JUNE 13, 2018

7:30 am - 9:00 am | **Continental Breakfast** | **Location:** Emerald Ballroom Promenade

BREAKOUTS (CHOOSE 1)

Retail Breakout Sessions | Location: Emerald I & II Ballroom

8:00 am – 9:15 am | **Lessons Learned from Large Community Hepatitis A Outbreaks**

This presentation describes the food safety and communication lessons learned from the recent large community outbreaks of hepatitis A in California and Michigan.

Moderator: Dionne Crawford, Food Safety Manager, US Supply Chain Management, McDonald's USA, LLC

Panelist:

Vince Radke, Sanitarian, Center for Disease Control and Prevention
Cory Hedman, VP, Food Safety & Quality Assurance, Meijer, Inc
Lisa Hainstock, Food Safety Specialist, Emergency Response and Enforcement Unit, Michigan Department of Agriculture & Rural Development
Mandy Sedlak, RS/REHS, Food Safety and Public Health Manager for EcoSure, Division of Ecolab

9:15 am – 10:00 am | **Entomophagy - An Introduction**

Back when I was a kid, there was this saying: "Nobody likes me, everybody hates me, I'm going to the garden to eat worms". Back then, it had an obvious negative connotation, but maybe the times have changed! Entomophagy – it's what's for breakfast (and lunch, and dinner)! This presentation will give you a basic understanding of entomophagy, as well as a look into its popularity, nutritional value, and economic potential. It may even make you pause and think a bit.

Moderator: Donna Wanucha, Retail Food Specialist, Office of State Cooperative Programs, U.S. Food and Drug Administration

Jim Dingman, Environmental Health Manager, City of Plano, Texas

10:00 am – 10:30 am | **Break | Location:** Emerald Ballroom Promenade

10:30 am – 12:00 pm | **Sushi as a Special Process in the Food Code**

Sushi concerns and controls from boat to throat. Our panel will be discussing how retail sushi operations control hazards of concern through the eyes of regulatory and industry experts.

Moderator: *Tara Camarada, President, Paster Training, Inc.*

"Safe Sushi" from a Producer Prospective
Thomas W. Nerney, Retail Food Specialist, U.S. Food and Drug Administration

Sushi Food Code Regulation
Dr. Larry Payton, Corporate Director of Quality Assurance, Sushic, LLC

Tips for Inspectors when Inspecting Sushi Operations
Catherine Feeney, Supervising Environmental Health Food Specialist, Center for Food Protection, Rhode Island Department of Health

11:30 pm – 1:30 pm | **Lunch On Your Own – Cash-N-Carry Lunches will be Available | Location:** G's Restaurant

AFDO Wants *Your* Feedback!

Daily evaluations are sent via email. We look forward to hearing from you!

Ticket required

Cannabis Breakout Sessions: | Location: Emerald III Ballroom

Moderator: Lezli Engelking, Founder, FOCUS: The Cannabis Health and Safety Organization

8:00 am – 9:45 am | **Status of Cannabis Legalization**

Much Ado About Nothing: Cannabis and the Current Administration

Lezli Engelking, Founder, FOCUS: The Cannabis Health and Safety Organization

Sean McClelland, Director of Government Relations, FOCUS: The Cannabis Health and Safety Organization

Cannabis Edible Programs: Food Safety and Cannabis Across the Country

Nine states and Washington D.C. have legalized cannabis for adult use but due to the fact that cannabis is federally illegal, there are no federal regulations or guidelines for states to adhere to. This discrepancy between state and federal policy has the ability to produce public health problems, particularly with food safety. This presentation describes the established retail cannabis programs in Alaska, California, Colorado, Nevada, Oregon, and Washington and examines how food safety regulations in each state differ between edibles and retail food.

Carmen Garson-Shumway, Student Worker Paraprofessional Sr. Position, Minnesota Department of Agriculture

How Cannabis-Derived Medications Go Through the FDA Approval Process: Development and Regulation

Securing approval from the Food and Drug Administration (FDA) is difficult for any investigational medication, but the challenges are even greater for products derived from botanical materials. In addition, there are additional hurdles and requirements for products containing substances that may affect the central nervous system (CNS). Multiple quality control steps, specifications (agreed to by FDA), and batch-to-batch consistency are required at each point along the way as the botanical raw material moves through various stages into a finished drug product. Since cannabis is classified in Schedule I of the Controlled Substances Act, special federal and state license and security requirements apply. Because cannabinoids have CNS activity, a full battery of abuse potential studies must be conducted. Upon FDA approval, a new cannabinoid product must be rescheduled under both state and federal law before it can be dispensed by pharmacies.

Alice Mead, Vice President of US Public Policy and Public Affairs for GW Pharma, Greenwich Biosciences

9:45 am – 10:15 am | **Cannabis Products: Keeping them Safe!**

Cannabis infused products are now available in most legal states. How do we monitor and manage their safety and keep our community safe? We'll explore the classic control points where intervention is most beneficial

Maureen McNamara, Founder & Chief Facilitator, Cannabis Trainers

10:15 am – 10:45 am | **Break | Location:** Emerald Ballroom Promenade

10:45 am – 11:45 am | **Challenges on Implementing a Cannabis Program**

Discussion on creating the regulatory infrastructure for a marijuana program, implementing an inspection program for marijuana-infused products manufacturers, and understanding Colorado's industrial hemp program.

Panelists:

Implementation of Rhode Island Medical Marijuana Program

Norman Birenbaum, Principal Policy and Economic Analyst, Rhode Island Department of Business Regulation

Marijuana Infused Edibles in Washington State

David Smith, Training & Compliance Manager, Washington State Department of Agriculture - Food Safety Program

Minnesota's Medical Model

Michelle Larson, MPA, Director of the Office of Medical Cannabis, Minnesota Department of Health

Navigating Industrial Hemp Regulations in Colorado

Thuy Vu, Founder & CEO, Thuy Vu Consulting, LLC

11:45 pm – 12:45 pm | **Regulatory Challenges in Cannabis Testing**

Discussion on Regulation development and requirement (Disparity), General needs for labs (per regulation, security, logistics, accreditation, etc), Method development and validation need (Challenges such as Matrices variety, single lab validation and multiple lab validation, PTs, reference material etc), Funding models (Industry versus government) and Final analytical results reporting in the realm of regulation, public health and consumer safety

Moderator: *Yvonne Salfinger, AFDO Chairperson, Laboratory, Science & Technology Committee*

Analytical Labs- Proficiency, Variance & Standardization

Ken Groggel, Director, Emerald Scientific Proficiency Testing Program

Cannabis is in the Weeds: Are You Ready for Testing

Susie Y Dai, Ph.D., University of Iowa

11:30 pm – 1:30 pm | **Lunch On Your Own – Cash-N-Carry Lunches will be Available | Location:** G's Restaurant

Ticket required

Drug & Medical Device Sessions

MONDAY, JUNE 11, 2018

MORNING JOINT SESSION

Moderator: Laurie Farmer, Director Office of State Cooperative Programs, U.S. Food and Drug Administration

7:30 am - 9:00 am	**Continental Breakfast** | **Location:** Emerald Ballroom Promenade
8:00 am - 8:15 am	**Announcements & Awards** | **Location:** Emerald Ballroom *Pamela Miles, AFDO President and Program Supervisor, Virginia Department of Agriculture and Consumer Services*
8:15 am – 9:30 am	**U.S. Food and Drug Administration Regulatory Affairs Update** | **Location:** Emerald Ballroom ORA's senior leaders will provide an update on significant operational changes and how things are working in the new program aligned organizational structure. They will also share information about key programmatic initiatives, as well as participate in a panel discussion with attendees. *Melinda Plaisier, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration* *Michael Rogers, MS, Assistant Commissioner for Human and Animal Food Operations, U.S. Food and Drug Administration* *Erik Mettler, MPA, MPH, Assistant Commissioner for Partnerships and Policy, U.S. Food and Drug Administration* *Alonza Cruse, Director, Office of Pharmaceutical Quality Operations, U.S. Food and Drug Administration* *Armando Zamora, Acting Director, Office of Enforcement and Import Operations, U.S. Food and Drug Administration*
9:30 am – 10:00 am	**Hurricane Maria and Puerto Rico's Response to Regulated Food and Drug Firms | Location:** Emerald Ballroom Hurricane Maria is regarded as the worst natural disaster on record in Puerto Rico. The tenth-most intense Atlantic hurricane on record and the most intense tropical cyclone worldwide of 2017. This session focuses on the challenges presented in the FDA regulated products arena during this hurricane. *Nicholas Scire, Consumer Safety Officer, U.S. Food and Drug Administration*
10:00 am - 10:30 am	**Break | Location:** Emerald Ballroom Promenade

Moderator: Dennis Baker, Retired, U.S. Food and Drug Administration

10:30 am - 11:15 am	**Using Artificial Intelligence to Advance Quality Operations**| **Location:** Diamond Ballroom

Representatives from Xavier University's 2017 Artificial Intelligence Summit working teams will explain how companies can use artificial intelligence to identify signals that can predict product failures. Participants will be engaged in discussing how they can realistically employ artificial intelligence solutions within their organizations using a crawl, walk, run scheme.

Mac McKeen, Fellow, Regulatory Science, Boston Scientific
Marla Phillips, Director, Xavier Health, Xavier University

11:15 am - 12:00 pm	**FDA is Rethinking the Handling of Reports Corrections & Removals** | **Location:** Diamond Ballroom

Do you know how benefit and risk inform FDA's evaluations of corrections and removals? Are you aware that FDA is substantially rethinking its approach, formally incorporating the factors outlined in its recent post market benefit-risk guidance document? This session will briefly overview the guidance and the benefit risk factors, and then provide deeper perspectives how these factors can change current practice. Overarching concepts and decision aids will be demonstrated and discussed.

Adam E. Saltman, M.D., Ph.D. Medical Officer, Office of Compliance, Center for Devices and Radiological Health, U.S. Food and Drug Administration

12:00 pm – 1:30 pm	**Lunch On Your Own – Cash-N-Carry Lunches will be Available** | **Location:** G's RESTAURANT
12:00 pm - 1:30 pm	**BURDITT LUNCH**| **LOCATION:** Lake Champlain Exhibition Hall Take a fun filled journey into AFDO's past, present and future. Your first stop will be 1915 where you will meet prominent AFDO members and supporters and hear their exact words that were delivered at the 19th Annual Conference held in Berkeley, California. A number of important actions and Resolutions came out of this conference including the association's expression of concern for misleading packaging, continued support for federal state cooperation, and a Resolution recommending states enact food safety requirements for all public eating establishments. Following a short visit to 1917 and 1943, we will salute all former and current Women who served as AFDO Presidents. Finally, we take a journey into the AFDO future to witness some very entertaining and interesting events.

Moderator: Cynthia Culmo, Principal Consultant, CC Consulting

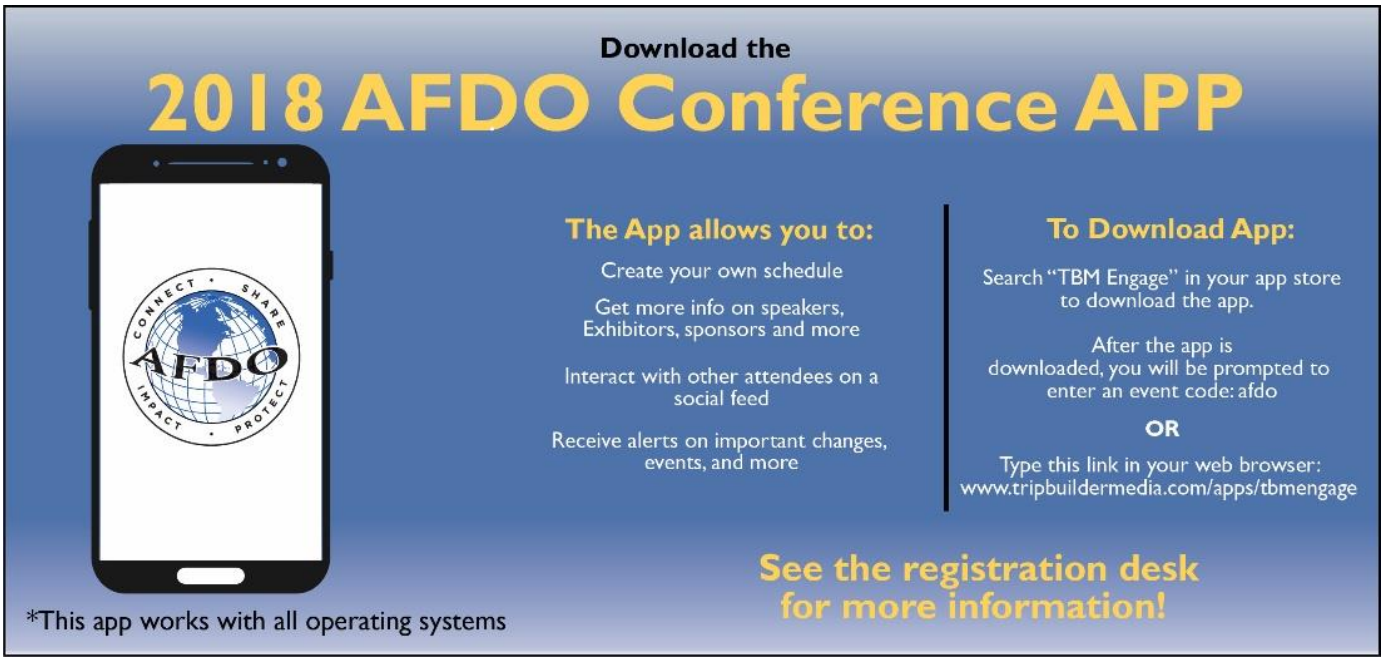
1:30 pm - 2:15 pm	**Health Canada update on the Modernization of Regulations for Self-Care Products**| **Location:** Diamond Ballroom

An update on the progress made by Health Canada in the modernizing of its approach to regulating self-care products. These products are available for purchase without a prescription and include cosmetics, natural health products and non-prescription drugs.

Matthew Bown, Senior Analyst, Consumer Health Product Modernisation, Natural and Non-Prescription Health Products Directorate, Health Products and Food Branch, Health Canada

Ticket required

2:15 pm - 3:00 pm	**Industry and USP Perspective on Supply Chain Control** | **Location:** Diamond Ballroom
As a member of the USP Expert Committee on Packaging, Storage, and Distribution, Bob Seevers will provide an industry perspective on current trends and expectations in supply chain control. The effort to protect the security and quality of medicines as they move through the supply chain is the subject of much recent work by industry and the United States Pharmacopeia. This presentation will offer perspective on recent FDA Guidances implementing the Drug Supply Chain Security Act an update in the United States Pharmcopeia's general chapters <659> on Packaging and Storage Requirements and <1079> Good Storage and Distribution Practices. *Robert Seevers, Senior Advisor, Pearl Pathways*	
3:00 pm – 3:30 pm	**Break | Location:** Emerald Ballroom Promenade
3:30 pm - 4:15 pm	**Structured Product Labeling and Product Labeling and Drug Supply Chain Integrity** | **Location:** Diamond Ballroom
This presentation will identify the current applications for which FDA is using the SPL format for submission of product and related data. Included in the presentation will be several example scenarios to demonstrate the direct relationship between the submission of current, accurate data in SPL format and the integrity of the drug supply chain. *Ken Coleman Stevenson II, VP Regulatory Affairs, Ceutical Laboratories, Inc*	
4:15 pm - 5:00 pm	**Enforcement Trends in Drugs, Devices & Compounding Pharmacy Inspections** | **Location:** Diamond Ballroom
What emerging compliance issues are likely to lead to regulatory action? Leadership from FDA's District and Division Offices will share the most notable trends in drug and device compliance including how inspection results drive compliance outcomes such as recalls, warning letters and related regulatory actions. *Diane Amador-Toro, New Jersey District Director, Pharma Program Division I Director, Office of Regulatory Affairs, U.S. Food & Drug Administration* *Maya Davis, Compliance Officer, U.S. Food and Drug Administration*	
6:00 pm – 10:00 pm	**Monday Night Event: "ENJOY THE JOURNEY"** Join us for a Sunset Dinner Cruise on Lake Champlain aboard the Spirit of Ethan Allen. A sumptuous buffet dinner, music, and a memorable evening awaits. The dining area is enclosed and fully climate controlled, but there is plenty of room on deck to enjoy the views of the Adirondack's, Green Mountains, Burlington and possibly a sighting of our lake monster "Champ." Be sure to have your camera ready. "It's always a beautiful day on the lake." Sponsored in part by the National Restaurant Association



Ticket required

TUESDAY, JUNE 12, 2018

MORNING JOINT SESSION

Moderator: Peter Salsbury, Project Manager, U.S. Food and Drug Administration

7:30 am - 9:00 am	**Continental Breakfast** | **Location:** Emerald Ballroom Promenade
8:00 am - 8:15 am	**Announcements & Business Meeting** | **Location:** Emerald Ballroom *Pamela Miles, AFDO President and Program Supervisor, Virginia Department of Agriculture and Consumer Services*
8:15 am – 8:45 am	**Public Health Crisis of Opioid Addiction** Communities all across the country have been facing the challenge of opioid addiction. Learn more about the four-year-old Hub and Spoke system in Vermont that has made a significant positive impact in many important personal and public health and safety indicators, and how this evidence-based work relates to regional and national public health efforts. *Mark Levine, MD, Commissioner, Vermont Department of Health*
8:45 am - 9:15 am	**Children with Intractable Seizures: The History of Cannabidiol and GW Pharmaceuticals** The political environment in the late 1990s with regard to attitudes toward cannabis, in both the U.S. and the U.K., was very different than it is now. A number of factors coalesced to make it possible for GW Pharmaceuticals (now Greenwich Biosciences in the U.S.) to be founded, making it the first company in the world to attempt to develop cannabis-derived prescription medications in accordance with regulatory standards for conventional pharmaceutical products. Since that time, significant research has been conducted, including robust preclinical research on cannabidiol (CBD) demonstrating in multiple animal models that CBD had anti-convulsant properties. This led patients and physicians to request CBD from GW, which resulted in the largest physician-initiated expanded (compassionate) access program in FDA's history and culminated in the first major randomized, placebo-controlled, double-blind clinical trial (RCT) program to have been conducted on CBD. *Alice Mead, Vice President of US Public Policy and Public Affairs for GW Pharma, Greenwich Biosciences*
9:15 am - 10:15 am	**Data Integrity** FDA depends heavily on the integrity of data generated in support of pre-approved applications and to confirm that medical products are manufactured in a manner to ensure their safety and effectiveness. This presentation will discuss the critical element of data integrity, data integrity and 21 CFR Part 11, FDA's increasing interest focusing on data reviews during surveillance inspections and recent FDA findings of data integrity issues. *Mike Chappell, Principal, Regulatory Compliance, Greenleaf Health LLC*
10:15 am – 10:30 am	**Break | Location:** Emerald Ballroom Promenade

Moderator: Shawn Beddes, Director, Global Quality, Younique

10:30 am - 11:00 am	**Health Canada's Role in the Management of Drug Shortages** | **Location:** Diamond Ballroom

Health Canada recently introduced regulations requiring the mandatory reporting of drug shortages and a website is in place for reporting and tracking of shortages. In addition, the Department has worked with other stakeholders in the management of shortages.

Linsey Hollett, Director, Health Product Compliance and Risk Management, Health Canada

11:00 am - 12:00 pm	**ISO 13485:2016 – Starting The Final Countdown** | **Location:** Diamond Ballroom

Last March, ISO issued the new version of ISO 13485:2016. All existing ISO 13485 certificates must be transitioned to the new version of the standard by February 28, 2019 – at the time of the AFDO Conference, the deadline will be less than a year away! Failing to meet this deadline can be costly, so it's in your interest to be ahead of the curve. Device quality expert Robert Ruff will walk you through the best practices to ensure you are on the right track in your transition plan. Attendees will learn:

- The transition plan for certificates
- The transition plan for the EU Harmonized Standard
- The role of ISO 13485:2016 in the MDSAP and Canada's plan to adopt it
- The major differences between ISO 13485:2003 and ISO 13485:2016

Akie Yamashita, Director, Medical Device, NSF International

Check out *the* Presentations

Presentations will be posted on the conference website following the conference

Ticket required

12:00 pm - 1:30 pm	**Working Lunch Presentation*** | **Location:** Diamond Ballroom

Handling Regulatory Challenges with Grace Under Pressure

During this session, attendees will be divided into teams. The teams will discuss how to handle both potential regulatory challenges and intra-office conflicts. Then a panel of seasoned professionals will comment on the attendees' responses.

Nancy Singer, President, Compliance-Alliance
Courtland Imel, CEO, Ceutical Labs
Daniela Drago, PhD, George Washington School of Medicine and Health Sciences
Julie Larsen, Senior Partner, BioTekenica
John Tomczak, Director of QA, BD Bard
Diane Amador-Toro, New Jersey District Director, Pharma Program Division I Director, Office of Regulatory Affairs, U.S. Food & Drug Administration
Adam E. Saltman, M.D., Ph.D. Medical Officer, Center for Devices and Radiological Health, Office of Compliance, U.S. Food and Drug Administration

***Lunch provided only for registered attendees of the Drug & Device Conference Track**

Ceutical Labs cGMP COMPLIANCE SPECIALISTS ***Sponsored by Ceutical Laboratories, Inc and BioTeknica** BIOTEKNICA ENGINEERING & REGULATORY SERVICES

Moderator: Ballard Graham, Retired, U.S. Food and Drug Administration

1:30 pm - 2:15 pm	**Aligning Hygienic Design Requirements with Inspections** | **Location:** Diamond Ballroom

Hygienically designed and maintained equipment, facilities and surfaces are the foundation for producing safe consumer goods. Medical devices, food, pharmaceuticals and supplement production standards frequently share codified requirements for GMPs and general hygienic practices. The equipment used to manufacture products can play a role in the safety of the product. This presentation will provide an overview of hygienic design principles for consideration in facility inspections

Angela Anandappa Ph.D., Director, Alliance for Advanced Sanitation, University of Nebraska-Lincoln

2:15 pm - 3:00 pm	**Quality System and Design Controls for Combination Products** | **Location:** Diamond Ballroom

Combinations Products are products comprised of one or medical products (drugs, biologics, and/or devices). Combination products present unique challenges for manufacturers since they may be subject to requirements in multiple current good manufacturing practice (CGMP) systems. This session will include a discussion of the device quality system (21 CFR 820) requirements for combination products containing devices, with an emphasis on the design control requirements (21 CFR 820.30). We will discuss topics such as the differences between design validation, design verification, and process validation.

M. Isabel Tejero del Rio, MD PhD, Center for Devices and Radiological Health, Office of Compliance, U.S. Food and Drug Administration

3:00 pm - 3:30 pm	**Break | Location:** Emerald Ballroom Promenade

3:30 pm - 4:15 pm	**Using Benefit Risk in Making Post Market Decisions** | **Location:** Diamond Ballroom

CDRH's mission is to protect and promote the public health, while assuring that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. This means that the benefit of device use should outweigh the risk. However, after a device is approved or cleared for the market, unforeseen circumstances can change the benefit-risk balance. Determinations regarding the best way to manage the problem can be helped by a consistent, transparent, and harmonized benefit-risk assessment. In this session, Dr. Saltman will discuss FDA's current thinking about using benefit-risk assessments in the post market arena, using medical device recalls as a working example.

Adam E. Saltman, M.D., Ph.D. Medical Officer, Office of Compliance, Center for Devices and Radiological Health, U.S. Food and Drug Administration

4:15 pm - 5:00 pm	**Compliance Question Panel** | **Location:** Diamond Ballroom

The compliance question and answer panel is made up of three distinguished representatives from the U.S. Food and Drug Administration and Health Canada who will answer compliance questions from industry participants. This is an excellent opportunity for industry to ask questions about their more difficult decisions, interpretations and applications of the regulations to their products. Questions will be answered directly by those who are decision makers in interpreting what practices are considered compliant and what is considered acceptable according to the regulations

Diane Amador-Toro, New Jersey District Director, Pharma Program Division I Director, Office of Regulatory Affairs, U.S. Food & Drug Administration
Mark Bailey, Supervisor, Medical Devices Inspection Program, Health Canada
M. Isabel Tejero del Rio, MD PhD, Center for Devices and Radiological Health, Office of Compliance, U.S. Food and Drug Administration

6:30 pm - 7:30 pm	**President's Reception | Location:** G's Restaurant
7:30 pm - 9:30 pm	**Wiley Award Banquet | Location:** Lake Champlain Exhibition Hall

AFDO Wants *Your* Feedback!

Daily evaluations are sent via email. We look forward to hearing from you!

Ticket required